

INFORMATION PAPER

MILVAX - VHCN
11 December 2013

SUBJECT: Hepatitis A Infection and Hepatitis A Vaccines

1. Purpose. To describe hepatitis A virus and the vaccines to prevent it.

2. Facts.

a. Microbiology. Hepatitis A virus (HAV) is a single-stranded RNA picornavirus. Picornaviruses are non-enveloped, positive-stranded RNA viruses with an icosahedral capsid; the protein shell that encloses the genetic material of the virus. Once the virus has infected the cell, it will start replicating using the mechanisms of the infected host cell. The primary site of HAV replication is in the liver where it is shed into the biliary ducts and eventually excreted in the feces.

b. Disease. The incubation period for HAV is approximately 28 days. The acute onset of symptoms may include fever, fatigue, nausea, jaundice (yellow skin or eyes), abdominal pain, loss of appetite, and dark urine. Acute illness typically does not last more than 2 months, but some individuals may relapse.

c. Epidemiology. Humans are the only natural reservoir for HAV and it is spread through direct person-to-person contact or after a person ingests the virus from contact with objects, food, or drinks contaminated by feces or stool from an infected individual. HAV occurs throughout the world and is most common in areas with poor food, water, and sanitation. It is endemic in some areas, particularly Central and South America, Africa, the Middle East, Asia, and the Western Pacific. HAV is one of the most common infections acquired during travel. Risk is highest for those who live in or visit rural areas, trek in the backcountry, or frequently eat or drink in settings of poor sanitation.

d. Vaccine.

(1) VAQTA[®] produced by Merck is an inactivated whole-virus vaccine. All formulations of the vaccine are preservative free.

(2) HAVRIX[®] produced by GlaxoSmithKline is an inactivated whole-virus vaccine. All formulations of the vaccine are preservative free.

(3) TWINRIX[®] produced by GlaxoSmithKline is a bivalent vaccine of inactivated hepatitis A virus and the purified surface antigen of the hepatitis B virus. The prefilled syringe tip caps and rubber stopper may contain latex. All formulations of the vaccine are preservative free.

e. Immunization.

(1) Administer HAVRIX[®] or VAQTA[®] as a two dose series with at least six months between the two doses. The pediatric (12 months - 18 years) dose is 0.5-mL and the adult (≥19 years) dose is 1-mL, both are administered as an intramuscular injection. The vaccines are

interchangeable and licensed for persons aged 12 months and older. The primary immunization should be administered at least two weeks prior to expected exposure to HAV.

(2) TWINRIX® is a three dose series administered at 0, 1, and 6 months. Alternative series timing should be in accordance with the package insert or ACIP guidelines. Each dose is 1-mL administered as an intramuscular injection in the deltoid.

(3) See the additional information paper on completing vaccine series with either Hep A/Hep B combination vaccine or the monovalent hepatitis A and hepatitis B vaccines at: www.vaccines.mil/documents/1504MIP-Hep%20A-B%20Counting%20Doses.pdf

f. Cautions. The hepatitis A vaccine should not be administered to individuals with a history of serious allergic reaction to a previous dose or to any component of the vaccine to include neomycin or yeast (TWINRIX® only). Use caution when vaccinating latex-sensitive individuals since all three vaccine prefilled syringe plungers and tip caps contain latex that may cause allergic reactions. All of the vaccine vial stoppers are latex free. It is recommended that those who are moderately or severely ill, or have an infection should postpone vaccination until they recover unless at risk for HAV infection. Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished immune response. Syncope can occur in association with vaccination and procedures should be in place to avoid falling injury.

g. Adverse Events. The most commonly reported adverse reaction following vaccination is injection site pain, erythema, and swelling. The symptoms are generally mild and self-limited. Mild systemic complaints to include headaches, malaise, fatigue, and low-grade fever are reported by fewer than 10% of those vaccinated.

h. DoD Policy. Unless seroimmune, administer hepatitis A vaccine to military personnel at initial entry training or upon deployment to HAV endemic areas.

3. References.

a. Centers for Disease Control and Prevention. Prevention of Hepatitis A through Active or Passive Immunization. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2006;55(RR07):1-23.

b. Multiple resources (e.g., product insert, Vaccine Information Statements) assembled by MILVAX - VHCN: www.vaccines.mil/hepA

Ms. Celia Dowers/ (703) 681-5668

Approved by: Dr Limone Collins